



Alliance SDC Updates

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Director, Alliance Data Management

CRP Information Session, November 2017

Presentation Objectives

- CALGB System Retirement Project
 - Scope and Deliverables
 - Timeline
 - Key Success Factors
 - Questions and Discussions
- Terminated Studies
- Central Monitoring
- RAVE Task Summary/Delinquency Report/Data Quality Portal (DQP)

CALGB Systems Retirement Project

- Achieve the Alliance Statistics and Data Center (SDC) 2012 grant objectives to consolidate the legacy cooperative group systems and retire aging systems
 - Move toward one data capture system - Rave for Legacy CALGB studies by mid-January 2018
- Begin consolidation of legacy NCCTG trials built in Ingres data capture system to Rave in early 2018
- Terminate trials whenever scientifically reasonable

Impact of Terminating Trials

- 20-30 trials have been terminated as part of this initiative
 - Alliance SDC will no longer accept forms for these trials
 - Close terminated studies to your local IRB
 - Do NOT close trials to the IRB prior to a termination notice

Welcome Jennifer



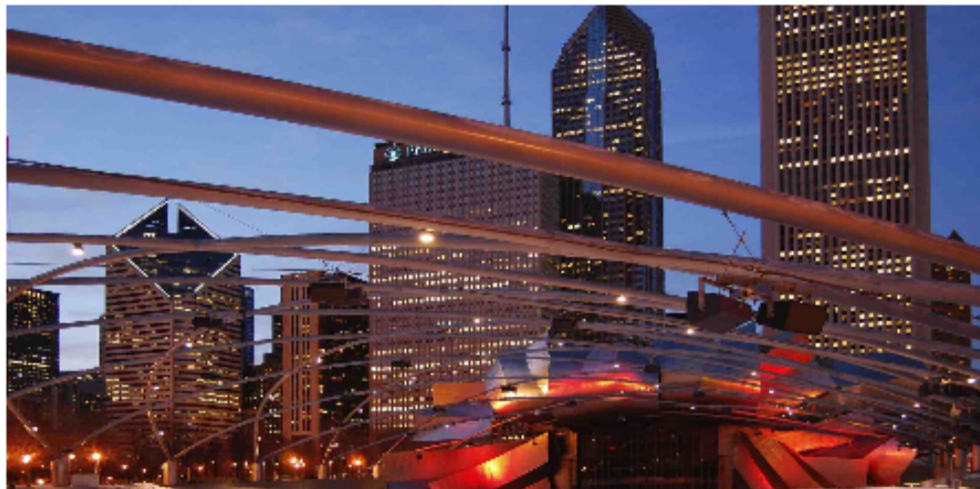
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ANNOUNCEMENTS

ONE WEEK AWAY AND COUNTING... 2017 Alliance Fall Group Meeting



If you haven't registered for the upcoming **2017 Alliance Fall Group Meeting** yet, now is a great time to do so. Visit the [Alliance Meeting Webpage](#) or [Cvent](#) for more details. If you have specific questions, please contact Samantha Berg, Alliance Meetings and Operations Coordinator, by e-mail sberg3@bwh.harvard.edu or phone (617) 525-3022. Also [meeting agendas](#) are now available. Presentations and other meeting materials will follow this week.



STUDY TERMINATIONS OF PATIENT FOLLOW-UP

- Alliance Terminated Studies Report - 10/15/2017
- ECOG-ACRIN Coordinated Studies Not Needing Further Data Submission - 12/01/2016
- Alliance Study Termination of Patient Follow-up Notices - 12/15/2014
- CALGB Studies with Termination of Patient Follow-up - 12/15/2013

Individual Notices:

- Termination of Patient Follow-up for N02C3 - 10/01/2017
- Termination of Patient Follow-up for CALGB 90401 - 09/01/2017
- Termination of Patient Follow-up for N00C9, N0735, N078D, N0923, N1085 - 08/15/2017
- Termination of Patient Follow-up for N02C4 and N08C9 - 07/15/2017
- Termination of Patient Follow-up for N0682 and Z1072 - 07/01/2017
- Termination of Patient Follow-up for CALGB 30605, CALGB 40502, CALGB 70305, A221301 - 06/15/2017
- Termination of Patient Follow-up for CALGB 70501 and CALGB 100001 - 06/01/2017
- Termination of Patient Follow-up for A051201 & A051202 - 05/01/2017
- Permanent Closure of CALGB 49805 (JMA17) - 05/01/2017
- Termination of Patient Follow-up for CALGB 30504 - 04/01/2017
- Termination of Patient Follow-up for N0871 - 04/01/2017
- Termination of Patient Follow-up for A091102 - 03/15/2017
- Termination of Patient Follow-up for Z0011, Z4033, CALGB 150007, CALGB 20206, CALGB 20801, CALGB 60805, CALGB 90202, CALGB 500105, N03CC, N0539, N063I, N0923, N07C2, N08C1,

What Can You Expect When Legacy Trials Transition to Rave?

- Notification memos posted on the Alliance and CTSU website
- All your data will be batch uploaded and viewable within Rave
- Rave invite from iMedidata
- All future data collection and amendments done through Rave

When Can You Enter Data in Rave?

- When you receive the bi-monthly posting that states you may resume data submission for the studies listed
- New data submitted by Teleform will not be processed and will be returned to the site
- Prior to this broadcast message please abide by the warning when accessing Rave

DO NOT Access Rave Prior to Memorandum










ATTENTION: Legacy data is being uploaded from Teleform. Do not enter or change any data on your subjects until this message no longer displays and you receive a notification of Rave readiness.

Find

[Advanced Search](#)

Site Group

Include Sub Site Groups

Site	Site Group	Site Number
 Abbott-Northwestern Hospital	World	MN008
 Abington Memorial Hospital	World	PA120
 Adena Regional Medical Center	World	OH182
 Advocate Christ Medical Center	World	IL026
 Advocate Sherman Hospital	World	IL015
 Akron General Medical Center	World	OH053
 Alegen Health Bergan Mercy Medical Center	World	NE017
 Alegen Health Immanuel Medical Center	World	NE025
 Allan Blair Cancer Centre	World	11076

Studies (585)



CALGB-140503 (Unavailable due to a Rave migration)

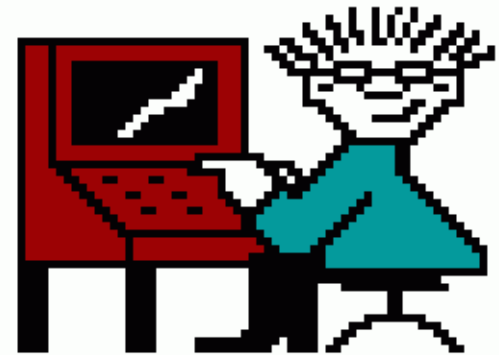


"I'm disappointed. If anyone should have seen the red flags, it's you."

Proposed Transition Date	Study #	Committee	Data Manager
10-1-2017	11001	Leukemia	Pam Fain Pribyl/Jenny Mentlick
10-1-2017	10801	Leukemia	Pam Fain Pribyl/Jenny Mentlick
10-1-2017	30406	Respiratory	Ryan Potaracke
10-1-2017	80802	GI	Ryan Potaracke
10-15-2017	80702	GI	Chris Bryhn/Melissa Heilman
10-15-2017	140503	Thoracic Surgery	Tasha McDevitt
10-15-2017	50904	Lymphoma	Andy Johnson
11-1-2017	90203	GU	Gina Grant
11-1-2017	30901	Respiratory	Tasha McDevitt
11-1-2017	50303	Lymphoma	Kayla Dietzenbach
11-1-2017	10701	Leukemia	Kayla Dietzenbach
11-1-2017	10403	Leukemia	Kayla Dietzenbach
11-15-2017	100104	Transplant	Andy Johnson
11-15-2017	90601	GU	Mist Bova-Solem
11-15-2017	11002	Leukemia	Kayla Dietzenbach
11-15-2017	80803	GI	Sasha Ford
12-1-2017	50403	Lymphoma	Andy Johnson
12-01-2017	100701	Transplant	Kayla Dietzenbach
12-01-2017	50803	Lymphoma	Andy Johnson
12-01-2017	40503	Breast	Sasha Ford
12-01-2017	49907	Breast	Sasha Ford
12-01-2017	40603	Breast	Melissa Heilman
12-15-2017	10603	Leukemia	Misty Bova-Solem
12-15-2017	100801	Transplant	Kayla Dietzenbach
12-15-2017	40601	Breast	Melissa Heilman
1-1-2018	30610	Respiratory	Andy Johnson
1-1-2018	50801	Lymphoma	Andy Johnson

Trials Requiring Your Help With Queries

- 80405 & 70807 – we need your help submitting data, so we can terminate these trials by December
- 80702 – the Data Manager will disregard all queries issued in Query Tracker – queries requiring attention will be issued in Rave



Central Monitoring Performed by the SDC

- Required Source Documentation Verification (SDV) in place for Ambassador (A031501) and Atomic (A021502)
 - Eligibility
 - Treatment (1st 2 cycles)
 - End Points
- Central Monitor will be required to document review of SDV in Rave
- Amended data breaks review flag and data will be re-reviewed
- Monitoring reports to be established

Data Management

Data Entry & Data Cleaning

- Expected and overdue materials (forms & queries) are tracked in numerous ways
 - Rave Task Summary
 - Reports available to sites on Alliance website
 - Data Quality Portal



Rave Task Summary

- Displays all pending tasks associated with the study
- High-level categories – status indicated by icon
 - Non-conformant Data
 - Open Queries
 - Overdue Data

Rave Task Summary

▼ Task Summary: Subject	Pages
▶ 🚨 NonConformant Data	0 📄
▶ 🤔 Open Queries	8 📄
▶ 🟡 Sticky Notes	0 📄
▶ 🕒 Overdue Data	7 📄

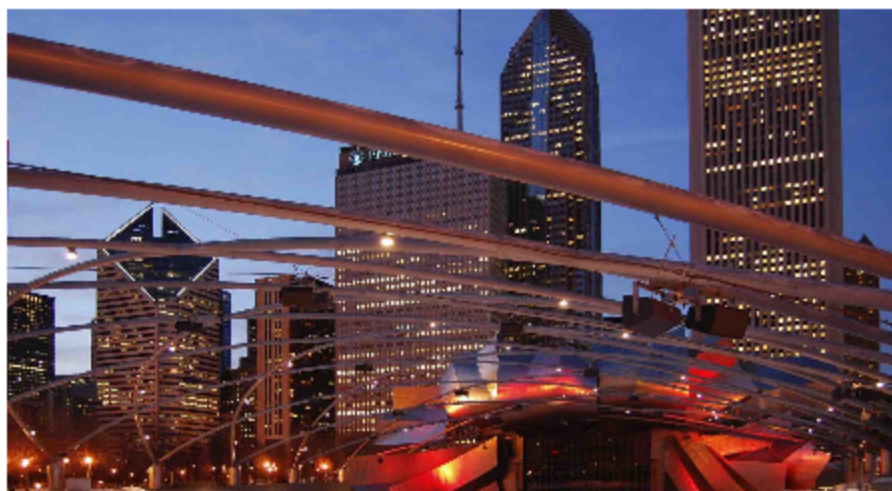
▼ Task Summary: Subject	Pages
▶ 🚨 NonConformant Data	0 📄
▼ 🤔 Open Queries	8 📄
- Treatment 01: Enzalutamatide alone 14-May-2015-Adverse Events: Solicited	
- Treatment 02: Enzalutamatide alone 12-Jun-2015-Adverse Events: Solicited	
- Treatment 03: Enzalutamatide alone -Patient Status: Treatment (Intervention)	
- Treatment 03: Enzalutamatide alone -Treatment (Intervention)	
- Treatment 04: Enzalutamatide alone -Patient Status: Treatment (Intervention)	
- Treatment 04: Enzalutamatide alone -Treatment (Intervention)	
- Treatment 01: Enzalutamatide alone 14-May-2015-Adverse Events: Other	
- Treatment 02: Enzalutamatide alone 12-Jun-2015-Adverse Events: Other	
1	
▼ 🟡 Sticky Notes	0 📄
▼ 🕒 Overdue Data	7 📄
- Treatment 03: Enzalutamatide alone -Laboratory Tests and Results	
- Treatment 03: Enzalutamatide alone -Adverse Events: Solicited	
- Treatment 03: Enzalutamatide alone -Specimen Submission: Blood (Substudies)	
- Treatment 04: Enzalutamatide alone -Laboratory Tests and Results	
- Treatment 04: Enzalutamatide alone -Adverse Events: Solicited	
- Treatment 04: Enzalutamatide alone -Specimen Submission: Blood (Substudies)	
- Treatment 01: Enzalutamatide alone 14-May-2015-Adverse Events: Other	
1	

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Data Management

Data Entry & Data Cleaning

- Example of Overdue Material Report

Patient, Initials, Date on, Last contact	Material	Item	Target Date	Overdue Date	Days Overdue
111111					
Hospital USA					
FML					
1/1/2015					
4/12/2017	Rave Query	Treatment 20: 07-Jan-2017, RECIST Measurements	02/24/2017	03/10/2017	38
	Rave Query	Treatment 20: 07-Jan-2017, RECIST Measurements	02/24/2017	03/10/2017	38

Patient, Initials, Date on, Last contact	Material	Item	Target Date	Overdue Date	Days Overdue
222222					
Oncology USA					
FML					
1/31/2011	Rave Form	Clinical Follow-Up 11: 21-Dec-2016, Supporting Documentation	12/27/2016	01/26/2017	81
12/24/2016					

Data Quality Portal (DQP)

- DQP does not include Ingres studies
- Forms will stay on the DQP Delinquent Forms tab if there is an outstanding system query
- DQP not yet available for sites – future tool



Access to iMedidata:

- Click this link to access iMedidata directly using Single Sign On (no login necessary)
- If you are having trouble accessing iMedidata using the Single Sign On link above, please try accessing via URL: <https://login.imedidata.com/selectlogin> (using your CTEP-IAM credentials)

Medidata Rave is a clinical data management system being used across the NCI Cancer Therapy Evaluation Program (CTEP) for the entry and management of clinical data for Network Group trials. The iMedidata application is a portal to access Medidata products including Rave. It allows site and Lead Protocol Organization (LPO) users to access studies across multiple Rave URLs by providing a single point of entry. Access to iMedidata and Rave is controlled through the CTEP-IAM system and through role assignments in the CTSU Regulatory Support System (RSS) for site users. To access iMedidata and Rave:

- Site staff will need to be registered with CTEP and have a valid and active CTEP-IAM account.
- This is the same account (user id and password) used for the CTSU members' website.
- To access studies in Rave, the site user must have been assigned one of the following Rave roles on the relevant LPO or Participating Organization roster:
 - Rave CRA role to enter subject data and respond to queries
 - Read-Only role to simply view data
 - Site Investigator role to enter subject data, respond to queries, and electronically sign forms
 - CRA (LabAdmin) role to enter subject data, respond to queries, and maintain local lab data
 - SLA role to simply view data, and maintain local lab data

Attention Rave users:

Information about browser compatibility, FAQs and known issues can be found at <https://learn.mdsol.com/mcc/about-browser-compatibility-81650569.html>

- [Learn More About Rave](#)
- [Rave Roles and Training](#)

DQP Summary Table

#	Protocol	Total Delinquencies	Total Queries
1	A011104	124	47
2	A011106	268	346
3	A011202	774	390
4	A011203	31	21
5	A011401	538	314
6	A011502	155	59
7	A021101	7	-
8	A021202	463	124
9	A021302	4	-
10	A021501	112	119

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Rave Studies

#	Protocol Number	Protocol Status	Rave Activation Date
1	APEC1621C	Active	26-Jul-2017
2	10012	Active	27-Apr-2017
3	10003	Active	23-Feb-2017
4	10007	Active	07-Apr-2017
5	ACNS1221	Closed to Accrual & Treatment	24-Dec-2013
6	ACNS1422	Active	02-Oct-2017
7	ABTC-1501	Active	07-Jul-2016
8	ABTC-1601	Active	07-Jun-2017
9	ABTC-1602	Active	29-Aug-2017
10	ABTC-1401	Temporarily Closed to Accrual	05-Jan-2016
11	ABTC-1402	Closed to Accrual	18-Dec-2015
12	ABTC-1403	Temporarily Closed to Accrual & Treatment	17-Dec-2015



DQP Delinquent Forms > Delinquency Aging Report Summary by LPO (ALLIANCE)

Notice

DQP is currently being piloted for a limited number of studies. More information will be available as more studies are added.

Delinquency Aging Report Summary for LPO ALLIANCE



Protocol	Total Delinquencies	< 15 Days	15 - 30 Days	31 - 60 Days	61 - 90 Days	> 90 Days	Last Refresh
A011104	124	23	10	10	25	56	10/27/2017 01:18 AM EDT
A011106	268	119	71	34	4	40	10/27/2017 01:18 AM EDT
A011202	774	93	76	92	82	431	10/27/2017 01:18 AM EDT
A011203	31	10	4	4	3	10	10/27/2017 01:18 AM EDT
A011401	538	112	68	118	84	156	10/27/2017 01:18 AM EDT
A011502	155	22	26	55	34	18	10/27/2017 01:18 AM EDT
A021101	7	4	-	-	-	3	10/27/2017 01:18 AM EDT
A021202	463	13	9	21	23	397	10/27/2017 01:18 AM EDT
A021302	4	-	-	-	2	2	10/27/2017 01:18 AM EDT
A021501	112	41	29	31	8	3	10/27/2017 01:18 AM EDT
A031102	96	25	15	13	9	34	10/27/2017 01:18 AM EDT
A031201	1598	156	117	169	124	1032	10/27/2017 01:18 AM EDT
A031203	17	-	5	2	3	7	10/27/2017 01:18 AM EDT
A041202	865	134	48	66	65	552	10/27/2017 01:18 AM EDT
A041501	2	2	-	-	-	-	10/24/2017 11:21 PM EDT
A051103	19	-	-	-	-	19	10/27/2017 12:17 AM EDT
A051301	60	4	2	7	14	33	10/27/2017 01:18 AM EDT
A061202	40	4	2	-	6	28	10/27/2017 01:18 AM EDT
A071101	25	-	-	3	-	22	10/27/2017 01:17 AM EDT
A071102	207	9	7	12	15	164	10/27/2017 01:18 AM EDT

Summary of Tools

- Rave Task Summary – Patient-level report
- Delinquency/Overdue – Membership-level report - includes all studies, regardless of the data capture system
 - Currently doesn't have the capacity for high-accruing studies
- Data Quality Portal (DQP) - Membership-level report for studies in the Rave data capture system

Questions?

